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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,415	09/12/2003	Andrew Vaillant	029849-0205	6654

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EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,415	VAILLANT ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *3-13 and 33-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,14-32 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *May 8, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-2, 14-32 and 38 are pending and under examination on the merits.

Response to Arguments

Rejections Withdrawn

Applicant's arguments, see pages 2-4, filed September 28, 2006, with respect to 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been fully considered and are persuasive. The rejection of claims 1-2, 14-32 and 38 has been **withdrawn**.

The rejection of claims 1-2, 14-32 and 38 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* studies, does not reasonably provide enablement for *in vivo* activity has been **withdrawn**. Applicant's arguments and the Declaration of Dr. Jean-Marc Juteau have been fully considered and are persuasive.

The rejection of claims 1-2, 14 and 17-32 under 35 U.S.C. 102(e) as being anticipated by Peyman et al. has been **withdrawn**. Applicant's arguments have been fully considered are persuasive.

Rejections Maintained

The rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Peyman et al. **is maintained**. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Peyman et al. (hereinafter Peyman) teaches that the efficacy of the tested oligonucleotides is dependant on the presence of a 10 guanines extension at each extremity of the oligonucleotides. In fact, Peyman teaches that the oligonucleotides activity can be improved by extending the oligonucleotides at the 3' and/or 5' end by **from <u>one</u> to ten** guanines (Column 2, lines 1-4). Therefore, Peyman does teach the instant claimed invention. Applicant argues that Peyman does not teach an oligonucleotide having an antiviral activity occurring by a non-sequence complementary mode of action. Peyman teaches that the oligonucleotide composition, 10-40 nucleotides in length, can be complementary to a target sequence or not complementary to the target sequence (column 45). Applicant also argues that Peyman adopts a "G quartet" structure which is not required in the present invention. Applicant is arguing about features which are not present in the instant claimed invention. Applicant further argues that Peyman does not teach a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection by administering an oligonucleotide having an antiviral activity occurring by a non-sequence complementary mode of action. Peyman teaches that the oligonucleotides are used to treat a disease caused by a virus (Abstract). This suggests that any virus infection can by treated by the oligonucleotides therefore Peyman does teach the instant claimed invention.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 14-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman et al. (US Patent 6,013,639, Jan. 2000).

The claimed invention is drawn to a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection in a subject, preferably a human, comprising administering at least one pharmacologically acceptable oligonucleotide at least 10 or 40 nucleotides in length wherein the anti-viral activity of said oligonucleotide occurs principally by a non-sequence mode of action, wherein the method comprises at least one antiviral randomer oligonucleotide, wherein said oligonucleotide is non complementary to any portion of the genomic sequence of RSV or parainfluenza virus, wherein said formulation has an IC_{50} for RSV or parainfluenza virus of 0.10 μM or less, wherein said oligonucleotide comprises: at least one modification; one phosphorothioated linkage and is in a formulation comprising a delivery system; at least one modification to the ribose moiety; at least one methylphosphonate linkage; at least one phosphorothiolated linkage and is in a formulation comprising a delivery system; wherein said oligonucleotide is a concatemer consisting of two or more oligonucleotide sequences joined by a linker, wherein said oligonucleotide is linked at one or more residues, to a molecule modifying the characteristics of the oligonucleotide to obtain one or more characteristics selected from the group of higher stability, higher antiviral activity, etc., wherein said oligonucleotide is double stranded, binds to one or more viral components, wherein at least a portion of the sequence of said oligonucleotide is derived from a viral genome, wherein the method comprises a mixture of at least two different antiviral oligonucleotides.

Peyman et al. discloses oligonucleotides where a nucleotide sequence is from 10 to 40 nucleotides in length and can be synthesized chemically. The oligonucleotides are used to treat diseases caused by viruses (Abstract). Stability can be effected by modifying or replacing the phosphate bridge (linkage). The most frequently used are phosphorothioate or methyl phosphonate bridges (Column 1, lines 25-35). Complete or partial replacement of the deoxyribose units, preferably, one, two, or three ribose units should be replaced ((column 4, lines 11-32). The oligonucleotides can be linked to molecules which are known to have a favorable influence on the properties of antisense oligonucleotides (column 4, lines 61-65). Oligonucleotides with chemical modifications demonstrate a higher cell uptake and increased stability (column 1, lines 38-50). The disclosed invention relates to the use of oligonucleotides possessing at least one terminal and modified pyrimidine nucleoside as diagnostic agents for detecting the presence or absence, or the quality, of a specific double-stranded or single-stranded nucleic acid molecule in a biological sample (column 6, lines 15-20).

Peyman teaches sense nucleotides, as well as antisense. While the antisense would be complementary, no part of the sense would be complementary to any part of the viral genome.

Peyman does not teach that the formulation has an IC_{50} for RSV or parainfluenza virus of 0.10 μM or less.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to optimize the formulation with a desired concentration for

effective anti-viral activity for the treatment of a viral infection. The person of ordinary skill in the art would have been motivated to make that modification because an effective amount of a pharmaceutical composition is required for treatment, and reasonably would have expected success because of the data from the *in vitro* experiments taught by Peyman.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the oligonucleotides to treat RSV or parainfluenza because the composition has been shown to be effective against viral infections. The person of ordinary skill in the art would have been motivated to use the pharmaceutical composition because Peyman has demonstrated that it is effective against diseases caused by viruses, and reasonably would have expected success because of the teachings of Peyman.

Conclusion

Due to the new grounds of rejection herein, this action is made nonfinal. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

January 19, 2007

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